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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,467	01/22/2002	Garry P. Nolan	A-64259-2/RMS/AMS	9737

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84.

Office Action Summary	Application No.	Applicant(s)	
	10/057,467	NOLAN, GARRY P.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 8-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 21 May 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/5/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the amendment filed 05 April 2004 claims 1-9 are listed as cancelled. It is apparent from the amendment filed 28 February 2002 and 05 April 2004 that only claims 1-7 have been cancelled. The statement that claims 1-9 are cancelled is considered to be a typographical error. In the future the applicants should begin the claims listing on a separate sheet of paper as required by 37 CFR 1.121(c)(1).

2. The amendment to the claims to recite "a cellular component endogenous to said cell" is not considered to be new matter. However because the specification does not define "a cellular component endogenous to said cell" the ordinary meaning of the phrase will be used for purposes of application of prior art. The phrase will be interpreted to mean a cellular component produced by said cell.

Information Disclosure Statement

3. The Information Disclosure Statement filed 05 April 2004 has been considered. The EP0440146A2 reference has not been considered because it is in a foreign language and no concise explanation of the relevance was provided. The statement that the reference corresponds to U.S. Patent No. 5,840,479 does not satisfy the requirement of 37 CFR 1.98 (a) (3)(i) because it is not clear how two documents correspond and the contents of the two documents is not necessarily the same. A statement describing the contents of EP0440146A2 would meet the requirements of 37 CFR 1.98 (a) (3)(i).

Specification

The objection to the specification in the Office action mailed 15 January 2004 is withdrawn in view of the amendment to the specification filed 05 April 2004.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (reference C21 in the information disclosure statement filed 09 May 2002) in view of Fearon et al. in view of Rayner et al. (reference C1 in the information disclosure statement filed 09 May 2002) in view of Gonda et al.

The claims are drawn to a method of screening for phenotypes in cells comprising a library of retroviral vectors comprising random sequences that express peptides comprising an amino-terminal glycine. In some embodiments the random sequences are sequences after selection and isolation, the cells are mammalian cells, the library comprises up to 10^9 members, the expressed peptide comprises a presentation sequence, and the vectors encode fusion proteins encoding a nuclear localization sequence.

Yang et al. shows in the abstract and throughout a yeast two-hybrid assay in which a library of random peptides are fused to a Gal4 domain (see figure 1). Binding of the random peptide to a retinoblastoma domain-Gal4 fusion protein results in an altered phenotype of the host cell due to expression of reporter genes HIS3 to produce a his^+ phenotype. On page 1154 Yang et al. shows that the library comprises 10^7 members. Yang et al. shows sequences of selected and isolated library members in Table 2. In the conclusion on page 1155, Yang et al. state that their method can be used to identify peptides with a desired binding affinity, to identify peptides that inhibit protein-protein interactions, and to study the phenotypic consequences of such interactions in living cells. In the conclusion on page 1155 Yang et al. further state that peptide variants can be at any position of an encoded polypeptide and can be embedded in a rigid presentation structure, and that their system has no size constraints on the expressed peptide. Yang et al. does not show use of a library of retroviral vectors, or mammalian host cells, or libraries of up to 10^9 members, or peptides with a nuclear localization sequence.

Fearon et al. shows a two-hybrid assay in mammalian cells in the abstract and throughout. Fearon et al. shows selection by phenotypes of chloramphenicol acetyl transferase expression, cell surface marker CD4 expression, or by hygromycin resistance. Fearon et al.

shows use of fusion proteins comprising a nuclear localization domain in the materials and methods section on page 7958. Fearon et al. shows analysis of cytoplasmic protein interactions in mammalian cells on pages 7959-7960. Fearon et al. shows activation by a fusion protein of a cell surface marker CD4 on pages 7960-7961 and figure 3. Fearon et al. shows use of a colon cDNA library comprising greater than 10^6 members to screen and select novel protein-protein interactions on pages 7961-7962. The selected cDNAs were sequenced. Fearon et al. concludes on page 7962 that their method has general utility to analyze protein interactions in mammalian cells, and in particular to screen cDNA libraries for protein interactions that can not be detected in yeast systems.

Rayner et al. shows retroviral vector cDNA libraries in the abstract and throughout. Rayner et al. shows on page 880 that retroviral vectors have advantages of efficiency and stable integration and expression, and allow for selection of phenotypes of infected cells. Rayner et al. show a cDNA library in their retroviral vector with 1.5×10^6 members on page 882. Rayner et al. shows screening infected mammalian T cells for acquisition of the phenotype of granulocyte-macrophage colony-stimulating factor (GM-CSF) independence in table 2. The sequence of isolated cells with the desired phenotype was determined as shown on page 885, and resulted in confirmation that IL-3 or GM-CSF expressing retroviral library members were in the selected cells. Rayner et al. concludes on page 886 that their method has general utility for isolation of any cDNA for which a functional screen can be devised, including differentiation along pathways that are not normally shown by a particular cell type.

Gonda et al. shows in the abstract and throughout that the amino terminal amino acid of a polypeptide controls the stability of the polypeptide in mammalian reticulocytes. Gonda et al.

shows that glycine is among the set of amino acids that confer the highest stability to polypeptides.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Yang et al. by use of mammalian cells and retroviral vectors because Fearon et al. shows that two-hybrid analysis may be extended from yeasts to mammalian cells so that libraries may be screened in mammalian cells for protein interactions that can not be detected in yeast systems, and because Rayner et al. shows that retroviral vectors are advantageous to screen libraries in mammalian cells because they are efficient and stably integrated. It would have been further obvious to construct the libraries of random peptides to contain an amino-terminal glycine residue because Gonda et al shows that amino-terminal glycines confer stability to polypeptides in mammalian cells. It would have been further obvious to construct polypeptides fused to nuclear localization sequences because Fearon et al. shows such fusion proteins in the context of assaying proteins for effects on phenotypes due to activation of gene expression in nuclei of mammalian cells. It would have been further obvious to use libraries of any desired size because Yang et al., Fearon et al., and Rayner et al. show analysis of libraries of 1 to 10 million members, and it is obvious to duplicate parts (see MPEP 2144.04).

8. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (reference C21 in the information disclosure statement filed 09 May 2002) in view of Fearon et al. in view of Rayner et al. (reference C1 in the information disclosure statement filed 09 May 2002) in view of Kauffman et al. (U.S. Patent No. 5,763,192, cited in the information disclosure statement filed 27 March 2003).

The claims are drawn to a method of screening for phenotypes in cells comprising a library of retroviral vectors comprising random sequences that express peptides. In some embodiments the phenotype is cell growth or cell death or a change in a differentiation marker.

Yang et al. shows in the abstract and throughout a yeast two-hybrid assay in which a library of random peptides are fused to a Gal4 domain (see figure 1). Binding of the random peptide to a retinoblastoma domain-Gal4 fusion protein results in an altered phenotype of the host cell due to expression of reporter genes HIS3 to produce a his^+ phenotype. In the conclusion on page 1155, Yang et al. state that their method can be used to identify peptides with a desired binding affinity, to identify peptides that inhibit protein-protein interactions, and to study the phenotypic consequences of such interactions in living cells. In the conclusion on page 1155 Yang et al. further state that peptide variants can be at any position of an encoded polypeptide and can be embedded in a rigid presentation structure, and that their system has no size constraints on the expressed peptide. Yang et al. does not show use of a library of retroviral vectors, or selection of phenotypes of cell death, cell growth, or a change in a differentiation marker.

Fearon et al. shows a two-hybrid assay in mammalian cells in the abstract and throughout. Fearon et al. shows selection by phenotypes of chloramphenicol acetyl transferase expression, cell surface marker CD4 expression, or by cell growth in the presence of hygromycin. Fearon et al. shows analysis of cytoplasmic protein interactions in mammalian cells on pages 7959-7960. Fearon et al. shows activation by a fusion protein of a cell surface marker CD4 on pages 7960-7961 and figure 3. Fearon et al. shows use of a colon cDNA library comprising greater than 10^6 members to screen and select novel protein-protein interactions on

pages 7961-7962. Fearon et al. concludes on page 7962 that their method has general utility to analyze protein interactions in mammalian cells, and in particular to screen cDNA libraries for protein interactions that can not be detected in yeast systems.

Rayner et al. shows retroviral vector cDNA libraries in the abstract and throughout. Rayner et al. shows on page 880 that retroviral vectors have advantages of efficiency and stable integration and expression, and allow for selection of phenotypes of infected cells. Rayner et al. shows screening infected mammalian T cells for acquisition of the phenotype of granulocyte-macrophage colony-stimulating factor (GM-CSF) independent growth in table 2. The sequence of isolated cells with the desired phenotype was determined as shown on page 885, and resulted in confirmation that IL-3 or GM-CSF expressing retroviral library members were in the selected cells. Rayner et al. concludes on page 886 that their method has general utility for isolation of any cDNA for which a functional screen can be devised, including differentiation along pathways that are not normally shown by a particular cell type.

Kauffman et al. shows in the abstract and throughout the use of libraries of expression vectors encoding random polypeptides to screen for desired phenotypes. Kauffman et al. shows in column 1 that their method may be used to select for a wide range of properties conferred by the random peptide. Kauffman et la. shows in column 12-13 selection of phenotypic properties that affect the survival of the host cell, and selection of polypeptides that catalyze a desired reaction or regulate gene expression in vivo.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Yang et al. by use of mammalian cells and retroviral vectors because Fearon et al. shows that two-hybrid analysis may be extended from

yeasts to mammalian cells so that libraries may be screened in mammalian cells for protein interactions that can not be detected in yeast systems, and because Rayner et al. shows that retroviral vectors are advantageous to screen libraries in mammalian cells because they are efficient and stably integrated. It would have been further obvious to modify the two-hybrid method by deletion of the two-hybrid reported gene elements of the assay and directly screening random peptides for conferred in vivo phenotypes because Yang et al. show that there is no constraint on the size or sequence of the random polypeptide sequence, and Kauffman et al. show such a direct selection of phenotypes beyond the limitations of the binding activities measured by the two-hybrid method. It would have been further obvious to measure phenotypes such as cell growth or death or differentiation because such phenotypes are suggested by Kauffman et al. and Rayner et al.

9. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Kauffman et al. as applied to claims 21-23 above, and further in view of Abbas et al. (reference C26 in the information disclosure statement filed 09 May 2002).

The claims are drawn to the method of claim 23 wherein the differentiation markers are characteristic of T cell or B cell activation.

Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Kauffman et al. as applied to claims 21-23 above does not show alterations of differentiation markers that are characteristic of T cell or B cell activation.

Abbas et al. reviews T cell and B cell differentiation particularly on pages 236-239.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to extend the screening of phenotypes of Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Kauffman et al. as applied to claims 21-23 above to determine states of differentiation of T cells and B cells because Abbas et al. shows that such differentiation is important in the function of the immune system, and such screening would allow researchers to gain further insights into the mechanisms of regulation of differentiation of T cells and B cells.

Response to Arguments

Applicant's arguments filed 5 April 2004 have been fully considered but they are not persuasive. The applicants state that the amendment to require an endogenous target for binding to the test peptides overcomes the rejections under 35 U.S.C. 103(a) because the references use binding targets that are expressed from recombinant DNA constructs rather than endogenous targets. However the targets shown in Yang et al. and Fearon et al. are nevertheless endogenous to the cells utilized by the cited articles. The targets of Yang et al. and Fearon et al are therefore considered to be endogenous targets. It is further noted that Rayner et al. does not use targets that have been constructed by recombinant DNA techniques and concludes on page 886 that their method has general utility for isolation of any cDNA for which a functional screen can be devised, including differentiation along pathways that are not normally shown by a particular cell type. Thus the prior art shows endogenous targets and further suggests use of any target for which a screen can be devised.

Terminal Disclaimer

10. The application/patent being disclaimed has been improperly identified since the number used to identify the application being disclaimed is incorrect. The correct number is 08/589911.

The terminal disclaimer disclaims over Application No. 09/859911 which is not commonly owned with the instant application. In addition, U.S. Patent No. 6,153,380, over which the instant application has been rejected, was not listed in the terminal disclaimer.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir.

1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

13. Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

14. Claims 8, 9, 11-17, 19, and 20-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-15, 19-21, and 27 of U.S. Patent No. 6,153,380 (reference A& in the information disclosure statement filed 09 May 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6,153,380 shows amino terminal glycine in column 10 and

measurement of growth, death, and T cell and B cell differentiation in columns 21, 32, and 33 as covered by the cited claims of the patent.

15. Claims 8, 11-17,. and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 27, 29, and 31-37 of copending Application No. 09/919635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application discloses amino terminal glycine as covered by the copending claims and otherwise claims species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 8-11, 14-17, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-26, 28-30, 34-37, 43, and 44 of copending Application No. 09/918601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 9-12, and 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-25, 28, 30-33, 34, and 39 of copending Application No. 09/916940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 8, 11, and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 08/589911. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application discloses amino terminal glycine as covered by the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (571) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.S. Brusca 13 May 2004

John S. Brusca
Primary Examiner
Art Unit 1631

jsb